DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 2, 2014

Nemera
Ms. Beatrice Grand Demars
Regulatory Scientist
600 Deerfield Parkway
Buffalo Grove, IL 60089

Re: K141664
Trade/Device Name: Safe'n'Sound® Staked Passive Delivery System – Cone Version
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe Accessory
Regulatory Class: II
Product Code: MEG
Dated: September 1, 2014
Received: September 5, 2014

Dear Ms. Grand-Demars:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141664

Device Name
Safe'n'Sound® Staked Passive Delivery System – Cone version

Indications for Use *(Describe)*
Single use device that is indicated for use as an accessory with sterile 1 mL-long staked needle prefilled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needle sticks. The devices can be used on a wide range of patients including children and adults.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary

Assigned 510(k) number:	K141664
Company:	Nemera 600 Deerfield Parkway Buffalo Grove, IL 60089 Phone: (800) 537-0178 Fax: (847) 325-3795
Contact:	Beatrice GRAND DEMARS
Date Prepared:	September 11, 2014
Trade/Proprietary Name:	Safe'n'Sound® Staked Passive Delivery System – Cone version
Classification Name:	Antistick piston syringe accessory
Classification/Product Code:	21 CFR 880.5860, Class II, Product Code MEG
Predicate Device:	K101233 Safe'n'Sound® Passive Delivery System by Rexam Healthcare
Device Description:	This submission is provided for modifications to the predicate device, which includes design changes and a plunger rod raw material change. For details, please refer to Attachment 1 for Design Modifications Rationale. The Safe'n'Sound® Staked Passive Delivery System – Cone Version is a single use anti-needle stick accessory for use with sterile 1 mL-long staked needle prefilled ISO Standard glass syringes. It fits with 1 mL-long staked syringes with a maximum needle length of ½" and consists of a subassembly (body, cone, sleeve, and spring) and a loose plunger rod.
Intended Use:	Single use device that is indicated for use as an accessory with sterile 1 mL-long staked needle prefilled ISO Standard glass syringes to aid in the protection of healthcare professionals, patients who self-inject doctor prescribed medications, and individuals that assist self-injecting patients, from accidental needle sticks. The devices can be used on a wide range of patients including children and adults.

Technological Characteristic Comparison Summary to Predicate Device:	The Safe'n'Sound® Staked Passive Delivery System – Cone version is similar to the predicate device in general technological features and principle of operation. Both are molded plastic subassemblies and plunger rod. Both have a spring that activates upon injection completion to fully contain the needle. However, the Safe'n'Sound® Staked Passive Delivery System – Cone version body part is split into two (2) components (Body and Cone). The proximal end of the body is slightly redesigned. These changes enable an enhanced view of the unit of measure. Sleeve design changes, including syringe clips (2 of 6) are reduced in size so that insertion force of the prefilled syringe is reduced. Change to a new polypropylene resin for the plunger rod, which is slightly stiffer to improve rigidity. These design changes have proven to be insignificant based upon design and process validations, bench testing, biocompatibility testing and simulated clinical use studies performed.
Performance Testing:	Bench testing has been performed on the Safe’n’Sound® Staked Passive Delivery System – Cone version. It confirmed the product functions as intended and is substantially equivalent to the predicate device. Biocompatibility testing performed demonstrates that the product meets ISO 10993-5 and ISO 10993-10 requirements.
Simulated Clinical Testing:	Simulated clinical use testing has been performed. It confirmed that the Safe’n’Sound® Staked Passive Delivery System – Cone version could be used safely and effectively to shield needles inside the protection device after use.
Conclusion:	Based upon the design, technology, performance, functional testing, and intended use, the Safe’n’Sound® Staked Passive Delivery System – Cone version is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act. The Safe’n’Sound® Staked Passive Delivery System – Cone version raises no new issues of safety or effectiveness.